



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 31, 2017

Katie P. Davis
Regulatory Affairs Manager, US
Syngenta Seeds, LLC – Field Crops - NAFTA
9 Davis Drive
P.O. Box 12257
Research Triangle Park, NC 27709

Subject: **Labeling Notification per Pesticide Registration Notice (PRN) 98-10** – Addition of alternative brand names, general housekeeping of items including entity name and address

Product Name: MIR604 Corn

EPA Registration Number: 67979-5

Application Date: November 30, 2016

OPP Decision Number: 532720

Dear Ms. Davis:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped “Notification” and will be placed in our records. The alternate brand name Agrisure® GT/RW has been added to the product’s records. The primary brand name of this product has been changed from Agrisure® RW Rootworm Protected Corn to MIR604 Corn and our records have been updated. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false

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or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

If you have any questions, please contact Matt Weiner of my team by phone at (703) 347-0333 or via email at Weiner.matthew@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a long horizontal flourish extending to the right.

Alan Reynolds, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-Incorporated Protectant Label

MIR604 Corn

Alternate Brand Name:

Agrisure® ~~RW Rootworm-Protected Corn~~ GT/RW

~~Plant-Incorporated Protectant:~~

Modified Cry3A Protein for Corn Rootworm Control

OECD Unique Identifier: SYN-IR604-5

This product is effective in controlling or suppressing damage caused by larvae of some corn rootworm species feeding on corn roots.

Active Ingredient:

Modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR604-5)..... ≤ 0.0029%*

Other Ingredients:

Phosphomannose isomerase and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR604-5)..... ≤ 0.00025%*

*Percentage in whole plants on a dry-weight basis.

Keep Out of Reach of Children

CAUTION

NOTIFICATION

67979-5

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

08/31/2017

EPA Registration No. 67979-5

Syngenta Seeds, LLC - Field Crops – NAFTA

EPA Establishment No. 66736-NC-001

Syngenta Seeds, Inc. –

~~Field Crops – NAFTA~~

~~P.O. Box 12257~~

~~3054 East Cornwallis Rd. 9 Davis Drive~~

Research Triangle Park, NC 27709

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

The following information regarding commercial planting must be included in the Grower Guide for ~~Agrisure® RW Rootworm Protected~~ MIR604 Corn.

Insect Resistance Management

Growers of ~~MIR604 Corn Agrisure® RW Rootworm Protected Corn~~ must plant a structured refuge of at least 20% non-corn-rootworm-protected Bt corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply corn-rootworm-labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the MIR604 Corn Agrisure® RW Rootworm Protected Corn field is treated in a similar manner.

Refuge planting options include: refuge acres should be planted as blocks adjacent to MIR604 Corn Agrisure® RW Rootworm Protected Corn fields, perimeter strips, or as in-field strips.

External refuges must be planted adjacent to (e.g., across the road from) MIR604 Corn Agrisure® RW Rootworm Protected Corn fields.

When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.

Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the MIR604 Corn Agrisure® RW Rootworm Protected Corn field is treated in a similar manner.

If the refuge is planted in a field that is in a crop rotation system, then MIR604 Corn Agrisure® RW Rootworm Protected Corn must also be planted in a field that is in a crop rotation system.

If the refuge is planted on continuous corn, then the MIR604 Corn Agrisure® RW Rootworm Protected Corn field may be planted on either continuous corn or in a field that is in a crop rotation system.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

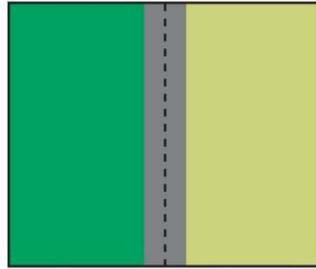
Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce a modified Cry3A protein for control or suppression of the following coleopteran insects:

- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica longicornis barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)

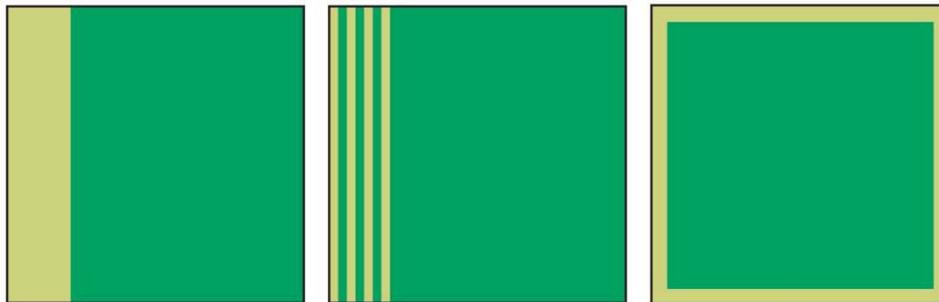
The following are schematics of the various refuge deployment options:

Adjacent



Can be separated by a road, path, ditch, etc., but not by another field.

Within



Block

Strips (Split Planter)

Perimeter

The following text and graphic indicating the refuge size requirement will appear on the MIR604 seed corn bags or bag tags.

**Important grower information.
Supplemental refuge planting requirement.**



For more information, please refer to Syngenta Stewardship Guide.